GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION

1620 I Street, NW Suite 800
Washington, DC 20006
(202) 833-9070
FAX (202) 833-9612

Alice E. Till, Ph.D.
President

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Drug Information Branch (HFD-210)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Draft Guidance for Industry on SUPAC-SS: Nonsterile Semisolid Dosage Forms, manufacturing Equipment Addendum [Docket No. 95D-0349]

Dear Sir or Madam:

On behalf of the Science Committee of the Generic Pharmaceutical Industry Association (GPIA), I would like to submit comments to you on "Draft Guidance for Industry on SUPAC-SS: Nonsterile Semisolid Dosage Forms, Manufacturing Equipment Addendum", 64 FR 518, January 5, 1999.

GPIA is comprised of the manufacturers and distributors of generic medicines, as well as the providers of technical services and goods to these firms. Several of our members will be directly impacted by implementation of the subject guidance.

As with the equipment addendum to other SUPAC documents, GPIA generally supports the agency's efforts to create this detailed summary of equipment. Furthermore, GPIA agrees with the content of the draft with respect to a) the identification of the categories of processing steps, and b) the definition and grouping of each class and subclass of equipment.

Some clarification is requested, however, and some edits are suggested. Additionally, other equipment examples are offered for inclusion in the various tables.

Add the following italicized items:

III. Mixing
  A. Definitions
    2. Operating Principles
      c. High-pressure Ultrasonic Mixing/Homogenizing: Mixing/homogenizing that employs high pressure and ultrasonic cavitation forces. The material is pumped through a specially designed orifice where it is subjected to shear, pressure and ultrasonic forces.
  B. Equipment Classification
    3. High-pressure Ultrasonic Mixer/Homogenizer: No subclasses have been identified.

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Table 3

Subclass Anchor/Sweepgate	*Olsa*
Subclass Dispersator	*Admix Rotoshear*
Subclass Ultrasonic	*Sonolator*

IV. Emulsification

A. Definitions

2. Operating Principles

iv. Employing the energy of ultrasonic vibration as a means of creating stable emulsions.

B. Equipment Classification

3. High Shear Emulsifiers

- *Ultrasonic*

Table 4

Subclass Rotor Stator	*Becomix*
	Maltomat
	Lee Trimix Turbo Shear
Subclass Ultrasonic	*Sonolator*

Table 5

Subclass Vacuum Vessel	*Olsa*
	Becomix
	Maltomat

VII. Packaging

A. Definitions

2. Operating Principles

c. . . and/or agitation *and/or circulation.*

c. . . peristaltic, *vacuum,* or piston pump.

Table 9

Subclass Mechanical/Crimping	*Kalish*

We would appreciate you consideration of these comments as the guidance is finalized.

Sincerely,

Alice E. Till, Ph.D.
President

Cc S. Hyden, Chair GPIA Science Committee
D. Miran, Chair Taskforce on Nonabsorbed Drugs